

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Mammography Quality Assurance Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: National Mammography Quality Assurance Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 19, 2004, from 9 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Charles Finder, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512397. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the following issues:

(1) Mechanisms to reduce the regulatory and inspection burden on facilities;

(2) Whether mammographic images obtained from reconstructed compressed digital data (lossless or lossy data compression) can be used for primary interpretation or storage;

(3) Whether images obtained from digitized film-screen mammograms can be used for primary interpretation or storage; and

(4) Revisions to Mammography Quality Standards Act (MQSA) compliance guidance.

The committee will also receive updates on recently approved alternative standards, full field digital mammography accreditation and certification, the inspection demonstration program, the status of MQSA reauthorization, and the new post inspection enforcement strategy.

The MQSA compliance guidance documents, which are in a question and answer format, are available to the public on the Internet at <http://www.fda.gov/cdrh/mammography>. This guidance is updated continually in response to questions that FDA receives from the public.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 5, 2004. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on April 19, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 5, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and

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addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks, Conference Management Staff, at 301-594-1283, ext. 105, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C., app. 2).

Dated: February 25, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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